

Amendment B And Request for Continued Examination
Appl. No. 09/909,691
September 7, 2004

REMARKS

Request for Continued Examination

Applicants request continued examination of the instant application under 37 C.F.R. 1.114 in view of the Notice of Appeal mailed February 5, 2004.

Claim Amendments

Claim 4 is canceled in this Amendment B. Claims 21-24 and 28-35 remain withdrawn. Upon entry of the amendment, claims 1-3, 6-20 and 25-27 will be pending in the application.

Rejection Under 35 U.S.C. § 103

Claims 1-4, 6-20 and 25-27 stand rejected under 35 U.S.C. §103(a) as obvious over any combination of:

1. WO 96/03113 in view of Hauer et al., U.S. Patent No. 5,866,159;
2. Hauer et al., U.S. Patent No. 5,866,159 in view of WO 96/03113; or
3. Hauer et al., U.S. Patent No. 5,866,159 in view of WO 99/49848.

The rejection is traversed for the reasons set forth below. Therefore, reconsideration and withdrawal are requested.

In order to establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine the teachings of prior art references; and the references, when combined, must teach all of the claim limitations. See MPEP 2143. As defined in independent claim 1, the present invention is directed to a self-emulsifying drug delivery system comprising a mixture of an extremely water-insoluble lipophilic agent, a fatty acid, a surfactant and a polyvinylpyrrolidone having a molecular weight of about 2,500 to about 20,000. In particular, as described at page 4, lines 3-14, Applicants have found that by using polyvinylpyrrolidone in the formulations of the present invention, a sufficient amount of an extremely water-insoluble active agent for therapeutic administration to an individual can be solubilized without precipitation of the drug under conditions simulated in the gastrointestinal tract. As further described below, none of the cited references remotely teaches or suggests a self-emulsifying drug delivery system for use with an extremely water-insoluble lipophilic agent

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that contains polyvinylpyrrolidone having a molecular weight of about 2,500 to about 20,000. Thus, Applicants submit that the cited references do not provide the necessary motivation or suggestion to combine the reference teachings; and, even if combined, the references do not teach all of the claim limitations of the present invention.

1. Hauer et al., U.S. Patent No. 5,866,159

Hauer et al., U.S. Patent No. 5,866,159, discusses the use of PVP as a thickening agent in a microemulsion comprising cyclosporine. However, nothing in the reference teaches or suggests the use of a low molecular weight PVP to increase the solubilization of an extremely water-insoluble active agent. In fact, Hauer et al. actually teach away from formulations of the present invention as the reference describes high molecular weight PVP for use as a thickening agent. Use of PVP as a thickener runs contrary to the present invention which solves the problem of drug precipitation in the gastrointestinal tract.

2. WO 96/03113

WO 96/03113 discusses a self-emulsifying drug delivery system comprising a water insoluble drug, a solubilizer, an emulsifier and oil. However, nothing in the reference remotely teaches or suggests the use of a low molecular weight PVP and the reference fails to teach any of the specific water-insoluble drugs of the present invention.

3. WO 99/49848

WO 99/49848 discusses a self-emulsifying dosage form of paclitaxel, a water-insoluble cancer drug. However, nothing in the reference remotely teaches or suggests the use of a low molecular weight PVP and the reference fails to teach any of the specific water-insoluble drugs of the present invention.

Because nothing in the cited references teaches or suggests the use of a low molecular weight PVP in a self-emulsifying drug delivery system for use with an extremely water-insoluble lipophilic agent, Applicants submit that the cited references do not provide the necessary motivation or suggestion to combine the reference teachings; and, even if combined, the references do not teach all of the claim limitations of the present invention. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness. Therefore, claims 1-3, 6-20

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and 25-27 are patentable over the cited references Hauer et al., WO 96/03113 and WO 99/49848.
Reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) is requested.

Rejection Under 35 U.S.C. § 112

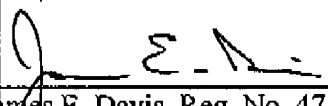
Claim 4 stands rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the invention. As described above, claim 4 has been canceled thereby mooting the rejection.

Conclusion

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore requests reconsideration of claims 1-4, 6-20 and 25-27. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (314) 446-7683.

The Commissioner is hereby authorized to charge \$2780.00 for the purchase of a five-month extension of time under 37 C.F.R. 1.136(a) and a Request for Continued Examination under 37 C.F.R. 1.114 to Deposit Account No. 08-0750. Further, if there is ever any other fee deficiency or overpayment in connection with this patent application, the Commissioner is hereby authorized to charge such deficiency or overpayment to Deposit Account No. 08-0750.

Respectfully submitted,


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